

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on March 7, 2006. No fee is due in connection with this Amendment. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-201 on the account statement.

Claims 8-20 are pending in this application. Claims 1-7 were previously withdrawn. In the Office Action, Claims 8-20 are rejected under 35 U.S.C. §103. In response Claim 8 has been amended. This amendment does not add new matter. In view of the amendment and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 8-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,578,336 to Monte ("Monte"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants have amended independent Claim 8 to recite, in part, a consumable tableted center and a coating comprising a medicament and the coating comprising at least 50% by weight of the product. The amendment is supported in the specification, for example, at page 10, lines 14-26. In addition, Claim 16 is directed to a consumable tableted center. Unlike chewing gum, the consumable tableted center is designed to dissolve in the mouth of the consumer and/or to be swallowed. Moreover, the center can be tableted so that it has a precise size (within an acceptable range) depending on the medicament or agent and shape. This allows an accurate control of the coating as well as allows one to produce products having specific sizes and shapes. In contrast, Applicants respectfully submit that *Monte* fails to disclose or suggest every element of Claims 8 and 16.

For example, *Monte* fails to disclose or suggest a consumable tableted center as required, in part, by Claims 8 and 16. Instead, *Monte* is entirely directed to chewing gum or soft candy products that have soft structures, which teach away from the present claims. See, *Monte*, column 1, lines 1-19. Moreover, a tableted product has distinguishable structure and components when compared to chewing gums or soft candies. In fact, they are made by entirely different manufacturing processes. *Monte* even teaches away from using hard confectionery centers. See, *Monte*, column 2, lines 36-37. Consequently, one having ordinary skill in the art would not arrive at the present claims in view of *Monte*.

In addition, *Monte* fails to disclose or suggest a coating comprising at least 50% by weight of the product. Instead, *Monte* only discloses that its product has coating layers. See, *Monte*, column 2, lines 62-67. Applicants respectfully submit that the Patent Office has failed to address Applicants' arguments regarding the reasons to have at least 50% by weight of the coating. Applicants have demonstrated the importance of the claimed coating levels. Consequently, the claimed coating levels are not conventionally used in the confectionery industry, and thus, these levels would not be obvious.

Applicants respectfully submit that *Monte* fails to even recognize the problems that Applicants' invention seeks to overcome. Applicants have surprisingly found that administering medicament through chewing, as opposed to swallowing, results in faster drug absorption through the oral mucosa. In this manner, an increase in the absorption of the medicament is achieved as well as an increase in the bioavailability of the drug as compared to typical oral administration. Indeed, the absorption approaches that of a parenteral administration, and the bioavailability is also much greater than oral administration.

Conventional consumable centers do not contain a significant amount of coating by weight of the product. As a result, in order to create a consumable center with a sufficient amount of medicament in a coating, certain levels of coating must be present in each consumable product to achieve the desired effect. By using such a high coating level, the level of medicament or agent in the coating can be selected so as to create, when the product is chewed, a sufficiently high concentration of the medicament or agent in the saliva. On the other hand, *Monte* fails to teach or recognize the need to deliver medicaments through the oral mucosa and therefore does not need its product to have at least 50% by weight of a coating as required by the present claims.

Applicants have discovered the novel way of delivering medicaments to an individual through the oral mucosa by using a consumable center having a medicament in a coating. The high coating level allows a sufficient amount of medicament to be delivered to a consumer, for example, to maintain the medicament in his mouth for a sufficient time to allow as much of the medicament into the saliva. The medicament in the saliva can then pass more readily through the oral mucosa in the buccal cavity, which favors faster drug absorption over oral ingestion. Applicants have carefully researched the desirability, applicability and levels of the coating and

medicament for such oral administration. Again, nowhere does *Monte* recognize or successfully employ the benefits of medicament absorption through the oral mucosa.

For at least the reasons discussed above, *Monte* fails to teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 8-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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